Rebuttal Report

W.R. Grace Bankruptcy Matter

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April 6, 2009

I am submitting this report resultant to the December 2008 expert report of Dr. Alan C. Whitehouse in the W. R. Grace Bankruptcy matter. The report will include the following essential components:

1) A discussion of the requirement that costophrenic angle blunting (as a radiographic finding) be present when making the determination that an individual has diffuse pleural thickening (DPT). I will also discuss the issue re: whether the width and extent of pleural thickening is important in determining the severity of DPT.

2) A discussion of the use of pulmonary function testing as a metric for determining pulmonary impairment.

I. DISCUSSION OF RADIOGRAPHIC INTERPRETATION AND DIFFUSE PLEURAL THICKENING: ANALYSIS OF THE GRACE/ACC PLAN OF REORGANIZATION, TRUST DISTRIBUTION PROCEDURE (TDP)

Diffuse pleural thickening can be seen on plain chest radiographs and on CT scan. According to the 2000 ILO classification system, diffuse pleural thickening by definition includes involvement of the costophrenic angle. If the costophrenic angle is not involved, pleural fibrosis is classified as localized (i.e. plaques). This revision by the ILO to its classification scheme was likely to lend additional certainty that diffuse pleural thickening was in fact present by requiring the costophrenic angle blunting, a common finding in those with diffuse pleural thickening. Although there is no way of knowing with absolute certainty, this notion of trying to gain additional certainty was also a motivating factor of requiring a minimum of 3mm pleural thickness before an x-ray is able to say a person's pleural is thickened. Less than 3 mm would be very difficult to distinguish from normal. In other words, a 3 mm threshold was used to

diminish the soft tissue (i.e. pleural fat) that can appear to some as "pleural thickening" but in fact is just a normal variant.

Further, the TDP category for "Severe Disabling Pleural Disease" defines diffuse pleural thickening as "at least extent 2...based on definition set forth in the 2000 revision of the ILO classification." According to the ILO classification, extent 2 is defined as total amount of pleural thickening exceeding one-quarter and up to one-half of the projection of the lateral chest wall." Pleural thickening, by definition, can be present as extent 1 (i.e. less than one quarter of the lateral chest wall but including costophrenic angle blunting), but the purpose of the TDP in this provision was, as the name implies, was to identify individuals with "Severe Disabling Pleural Disease" which would include those with extent 2 or greater disease.

The primary reasons for defining severe pleural disease this way is to assure that, one, a person actually has radiographic findings that cannot be confused with other diseases or normal variants (e.g. confusing pleural fat with DPT or pleural plaques) and, two, that the radiographic finding, if DPT, is likely to cause functional impairment. This distinction is particularly important given that differences in the prognostic and functional implications of having DPT vs. pleural plaques are so profound.

With regard to being sure the radiograph actually shows DPT, the TDP accomplishes this goal by including in its definition of DPT as including CAO. This is not only the viewpoint of the International Labour Organization in its 2000 Classification scheme but also supported by the medical literature. Ameille and colleagues (1) addressed a very similar issue in their 2004 publication. By using a definition of DPT as being necessarily associated with CAO, the researchers found that agreement among readers was significantly better. Furthermore, because CAO commonly occurs as a result of a pleural effusion and leads to fusing of the visceral and

parietal pleural surfaces that is the pathophysiologic hallmark of DPT, it make sense then to include CAO as a necessary element when making a radiographic diagnosis of DPT. Also, as in our studies quoted below, a similar reduction in lung function has been found when CAO and DPT are considered separately, lending credence to the idea that the two findings result in the same functional consequences (2, 3).

II. DISCUSSION OF THE USE OF PULMONARY FUNCTION IN LUNG DISEASE DIAGNOSIS

Background on Pulmonary Function Tests

The proper performance and interpretation of pulmonary function tests can be found in various ATS publications [e.g. Official Statement of the American Thoracic Society, "Lung Function Testing: Selection of Reference Values and Interpretative Strategies," 144 American Review of Respiratory Disease 1202-1218 (1991); Official Statement of the American Thoracic Society, "Standardization of Spirometry: 1994 Update," Am J Resp Crit Care Med 152: 1107-1136 (1995); Official Statement of the American Thoracic Society, "Single-breath Carbon Monoxide Diffusing Capacity (transfer factor): Recommendations for a Standard Technique - 1995 Update," Am J Respir Crit Care Med 152:285-298 (1995)]. The factors influencing the proper performance of PFTs is highly technical, and a discussion describing all of the ATS criteria is beyond the scope of this report. However, it is critically important that these tests be performed and interpreted correctly if one is to rely upon their results for impairment determinations. If the tests are not valid and reproducible, there exists the potential to assign impairment to someone who would not be considered impaired if the tests were performed properly.

Spirometry

Spirometry is the most commonly administered component of the pulmonary function testing. Spirometry measures airflow, which is expressed as volume exhaled per unit of time. In doing so, spirometry is able to distinguish among people who have no impairment and those who have either a restrictive or an obstructive lung disease. The most important spirometric measurements are the forced vital capacity (FVC), forced expiratory volume in the fist second (FEV_1), and the FEV_1/FVC ratio. Forced vital capacity is the total volume of air that is exhaled on a maximal exhalation effort by the patient. FEV_1 is the volume of air expired in the first second of the FVC maneuver. In patients with obstructive lung disease, such as emphysema, the FEV_1/FVC ratio is reduced. Conversely, in those patients with restrictive disorders, such as asbestosis, the FEV_1/FVC ratio is increased. While other lung diseases can cause either an obstructive or restrictive impairment, spirometry allows one to put diseases into one of these two broad categories.

The ATS has promulgated certain criteria for administering and interpreting spirometry tests, such as:

1. **There should be 3 traces available for review in order to assess patient effort, end of exhalation, and repeatability to determine if there is an obvious end of exhalation, demonstrated by a plateau for at least one second after an exhalation time of at least 6 seconds.**

2. **Because this determination requires the PFT interpreter to examine the actual efforts made by the worker in graphic form, the ATS requires that the spirometry graphs be of sufficient size in order that someone interpreting the exam can discern whether there is testing artifact, such as coughing, sneezing, or delay in exhalation.**

3. **In order to be sure that the tests are reproducible, the largest and second largest FEV-1 and FVC must be within 0.15 liters of each other.**

Note: Whitehouse did not provide sufficient information to assess any of these criteria.

Diffusing Capacity

The diffusing capacity test (DLCO) is performed separately from spirometry and is a measurement of gas exchange capability of the lung. Specifically, DLCO measures the ability of the gas exchange membrane to diffuse carbon monoxide. This test will provide information about the ability of the lung to absorb oxygen. The DLCO is a highly sensitive, non-specific test of pulmonary function. As such, it cannot, by itself, be used to make a diagnosis (Whitehouse Deposition, page 262). In diseases that impair oxygenation, such as emphysema and a variety of interstitial lung diseases, the DLCO will be reduced.

Tests of diffusing capacity may be indicated for:

1) Evaluation and follow-up of parenchymal lung diseases including: idiopathic pulmonary fibrosis (IPF, also known as usual interstitial pneumonitis, or UIP) and bronchiolitis obliterans organizing pneumonia (BOOP, or cryptogenic organizing pneumonia, COP), diseases associated with dusts such as asbestos, or drug reactions (eg,from amiodarone) or related to sarcoidosis; and for quantification of disability associated with interstitial lung disease

2) Evaluation and follow-up of emphysema and cystic fibrosis; and differentiating among chronic bronchitis, emphysema, and asthma in patients with obstructive patterns; and for quantification of impairment and disability.

3) Evaluation of cardiovascular diseases (eg, primary pulmonary hypertension, acute or recurrent thromboembolism, or pulmonary edema)

4) Evaluation of pulmonary involvement in systemic diseases (eg, rheumatoid arthritis, systemic lupus erythematosus)

5) Evaluation of the effects of chemotherapy agents or other drugs (eg, amiodarone, bleomycin) known to induce pulmonary dysfunction

6) Evaluation of pulmonary hemorrhage

7) As an early indication of certain pulmonary infections (eg, pneumocystis pneumonia)

8) Prediction of arterial desaturation during exercise in some patients with lung disease

Factors that Result in a Decrease in DLCO	
Factor	**Condition Giving Rise to Factor**
Deficiency in red blood cells	Anemia
Loss of pulmonary capillary bed with relatively normal lung volume	Multiple pulmonary emboli, early collagen-vascular disease, early sarcoidosis, military tuberculosis
Loss of functioning alveolar-capillary (A-C) bed with increased lung volume	Emphysema
Loss of functioning A-C bed with decreased lung volume	Parenchymal restrictive processes including pulmonary resection, idiopathic interstitial fibrosis, asbestosis, scleroderma lung disease, histiocytosis-X, sarcoidosis, pneumonia
Failure of inspired air to reach alveoli, or poor distribution of ventilation with low, normal or increased lung volume	Seen occasionally with severe obstruction during asthmatic or bronchitic attack; seen frequently with emphysema and poor effort

In addition to spirometry standards, the ATS also has criteria for the determination of the diffusing capacity. As is the case with the spirometry values, failure to perform the DLCO test

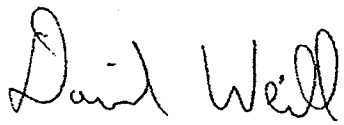
properly leads to unreliable test results that cannot be relied upon when making impairment judgments. The following describes the technical factors involved with the performance of the DLCO that may reduce the reliability of the DLCO measurement:

1) **Inspired Volume is not 90% of the largest previously measured vital capacity.** The ATS DLCO requires that an individual's inspired volume be at least 90% of the largest previously measured vital capacity. This criterion relates to the degree to which the patient adequately performed the test.

2) **Washout volume is inside the dead space.** The ATS DLCO requires that the washout volume be outside the dead space: "If a continuous gas analyzer system is used, computerized or manual inspection of the expired CO and tracer gas curves may be used to adjust washout volume to assure dead space clearance." ATS DLCO at 2190. An individual plaintiff's pulmonary function test would fail this requirement if the washout volume is inside the dead space on all trials of the DLCO test.

3) **There are not two acceptable DLCO trials.** The ATS DLCO requires two acceptable DLCO trials. An individual would not meet this criterion if there are no acceptable trials during which the inspired volume is not at least 90% of the largest previously measured vital capacity and the washout volume is inside the dead space.

Note: There is no information in any of Whitehouse's reports that allows us to determine if he complied with any of these criteria.



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